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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.    | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------|------------------|
| 09/805,816   | 03/13/2001  | Mohammad A. Heidaran | 07078-030001           | 6205             |
| 22434  | 7590        | 04/16/2004           | EXAMINER               |                  |
| BEYER WEAVER & THOMAS LLP<br>P.O. BOX 778<br>BERKELEY, CA 94704-0778 |             |                      | DI NOLA BARON, LILIANA |                  |
|  |             | ART UNIT             | PAPER NUMBER           |                  |
|  |             | 1615                 |                        |                  |
| DATE MAILED: 04/16/2004  |             |                      |                        |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|------------------------------|------------------------|---------------------|--|
|                              | 09/805,816             | HEIDARAN ET AL.     |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Liliana Di Nola-Baron  | 1615                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 06 February 2004.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1,2,10,20,21 and 24-26 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1,2,10,20,21 and 24-26 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All    b)  Some \* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.  
\_\_\_\_\_

## DETAILED ACTION

Receipt of Applicant's request for continued examination and amendment, filed on February 6, 2004, is acknowledged.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 20, 21 and 24-26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,586,406 in view of Atkinson et al. (U.S. Patent 6,514,514).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the patent and the instant application are directed to methods for inducing chondrogenesis in vivo (See instant claim 25) comprising the step of exposing or culturing joint tissue cells (chondrocytes) to a matrix composition comprising type I or type II collagen and GDF-5. The "comprising" language of the instant claims allows for the presence of additional materials, such as hyaluronate, in the compositions of the patented claims. The instant claims differ from the patented claims in the fact that the instant claims recite that the step of culturing

is done in vitro, whereas the patented claims do not recite said limitation. Tissue culture is routinely done in vitro, therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to culture chondrocytes in vitro, as claimed in the instant application. With regard to instant claim 26, the patent's specification at col. 3 teaches that the collagen fibers are dispersed and then lyophilized (See lines 53-67). Claim 26 cannot be considered patentably distinct over claims 1-4 in the patent when there is a specifically recited embodiment in the patent that would anticipate claim 26. With respect to instant claims 20, 21 and 24-26, the patented claims are deficient in the sense that they do not include BMP-4 in the compositions and method of the invention.

Atkinson et al. discloses culturing in vitro a cartilage repair matrix comprising type I and type II collagen with chondrocytes in the presence of chondrogenesis-enhancing proteins prior to implantation into a cartilage lesion in vivo (See col. 22, lines 8-16, col. 21, lines 39-56, and col. 18, lines 23-54), and includes BMP-4 among the chondrogenesis-enhancing proteins used in the invention (See col. 8, line 60 to col. 9, line18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and compositions patented in U.S. Patent 6,586,406, by including BMP-4, as claimed in the instant application. The expected result would have been an enhancement in chondrocyte's growth. Because of the teachings of Atkinson et al., that BMP-4 stimulates chondrogenesis, one of ordinary skill in the art would have a reasonable expectation that the method claimed in the instant application would be successful at stimulating the growth

of chondrocytes. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

3. Claims 20, 21 and 24-26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, and 6-9 of copending Application No. 10/444640 in view of Atkinson et al. (U.S. Patent 6,514,514). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the pending application and the instant application are directed to methods for inducing chondrogenesis comprising the step of exposing or culturing joint tissue cells (chondrocytes) to a matrix composition comprising type I or type II collagen and GDF-5. With regard to instant claim 26, the specification of the pending application at page 6 teaches that the collagen fibers are dispersed and then lyophilized (See lines 18-30). Claim 26 cannot be considered patentably distinct over claims 1, 2 and 6-9 in the pending application when there is a specifically recited embodiment in the pending application that would anticipate claim 26. With respect to instant claims 20, 21 and 24-26, the pending claims are deficient in the sense that they do not include BMP-4.

Atkinson et al. discloses culturing in vitro a cartilage repair matrix comprising type I and type II collagen with chondrocytes in the presence of chondrogenesis-enhancing proteins prior to implantation into a cartilage lesion in vivo (See col. 22, lines 8-16, col. 21, lines 39-56, and col. 18, lines 23-54), and includes BMP-4 among the chondrogenesis-enhancing proteins used in the invention (See col. 8, line 60 to col. 9, line 18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and compositions claimed in copending application 10/444640, by including BMP-4, as claimed in the instant application. The expected result would have been an enhancement in chondrocyte's growth. Because of the teachings of Atkinson et al., that BMP-4 stimulates chondrogenesis, one of ordinary skill in the art would have a reasonable expectation that the method claimed in the instant application would be successful at stimulating the growth of chondrocytes. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

This is a provisional obviousness-type double patenting rejection.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1, 2, 10, 20, 21 and 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claims 1, 2, 10, 20, 21 and 24-26, the phrase "enhancing" renders the claims indefinite, because it is not clear how chondrogenesis is enhanced.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 2, 10, 25 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by Atkinson et al. U.S. Patent 6,514,514).

Atkinson et al. discloses culturing in vitro a cartilage repair matrix comprising type I and type II collagen with chondrocytes in the presence of chondrogenesis-enhancing proteins prior to implantation into a cartilage lesion in vivo (See col. 22, lines 8-16, col. 21, lines 39-56, and col. 18, lines 23-54), and includes BMP-4 among the chondrogenesis-enhancing proteins used in the invention (See col. 8, line 60 to col. 9, line 18). Thus, the patent fully discloses the subject matter claimed in instant claims 1, 2 and 25. Chondrocytes are from joint tissue, as claimed in claim 10. With regard to claim 26, the patent teaches that a slurry (dispersion) of collagen is lyophilized until dry (See Example 4).

The method and compositions disclosed by Atkinson et al. meet the limitations of claims 1, 2, 10, 25 and 26 of the instant application, as the patent provides a method for stimulating chondrogenesis as claimed by Applicant. Thus, the patent anticipates the claimed invention.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 2, 10 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Radice et al. (U.S. Patent 6,699,471).

Radice et al. provides a method comprising culturing chondrogenic cells isolated from articular cartilage (joints) in an extracellular matrix comprising fibers of type II collagen in the presence of BMP-4 (See col. 13, line 26 to col. 14, line 58).

The method and compositions disclosed by Radice et al. meet the limitations of claims 2, 10 and 25 of the instant application, as the patent provides a method for stimulating chondrogenesis as claimed by Applicant. Thus, the patent anticipates the claimed invention.

#### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 20, 21 and 24-26 are rejected under 35 U.S.C. 103(a) as being obvious over Heidaran et al. (U.S. Patent 6,586,406) 406 in view of Atkinson et al. (U.S. Patent 6,514,514).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The patent discloses methods for inducing chondrogenesis in vivo (See instant claim 25) comprising the step of exposing (i.e. culturing) joint tissue cells (chondrocytes) to a matrix composition comprising type I or type II collagen and GDF-5 (See cols. 3-4 and claims 1-4).

The “comprising” language of the instant claims allows for the presence of additional materials, such as hyaluronate, in the compositions disclosed by the patent. With regard to instant claim 26, the patent’s specification at col. 3 teaches that the collagen fibers are dispersed and then lyophilized (See lines 53-67). With respect to instant claims 20, 21 and 24-26, the patent is deficient in the sense that it does not include BMP-4 in the compositions and method of the invention.

Atkinson et al. discloses culturing in vitro a cartilage repair matrix comprising type I and type II collagen with chondrocytes in the presence of chondrogenesis-enhancing proteins prior to implantation into a cartilage lesion in vivo (See col. 22, lines 8-16, col. 21, lines 39-56, and col. 18, lines 23-54), and includes BMP-4 among the chondrogenesis-enhancing proteins used in the invention (See col. 8, line 60 to col. 9, line18).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method and compositions disclosed by Heidaran et al. in U.S. Patent 6,586,406, by including BMP-4, as taught by Atkinson et al. The expected result would have been an enhancement in chondrocyte’s growth. Because of the teachings of Atkinson et al., that BMP-4 stimulates chondrogenesis, one of ordinary skill in the art would have a reasonable expectation that the method claimed in the instant application would be successful at stimulating the growth of chondrocytes. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Response to Arguments***

12. Applicant's arguments filed on February 6, 2004 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*SP&3*

April 14, 2004

*T. K. Page*  
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